K102913

MAY - 6 2011

COVIDIEN

510(k) Summary

510(k) Summary
Date Prepared: 4/28/2011

1. Submitter Information:

Covidien
Energy-based Devices
Formerly known as Valleylab, a Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301

Contact: Ben Cordileone
Regulatory Affairs Manager
Phone: 303-530-6396
Fax: 303-516-8307
Email: ben.cordileone@Covidien.com

2. Name of Device

Trade name: ForceTriad™ Electrosurgical Generator
Common/Classification name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

3. Predicate Device

The ForceTriad™ is substantially equivalent to the original ForceTriad™ submitted under K051644. The intended use, basic features and operation remain the same as the previously cleared ForceTriad™.

4. Device Description

The ForceTriad™ generator is a full-featured electrosurgical generator with monopolar, bipolar, and LigaSure™ vessel sealing outputs. The generator is an electrically isolated, microcontroller-based device, incorporating closed-loop control for all output modes implemented in the microcontroller firmware. The generator incorporates Instant Response™ technology to constantly measure the electrical impedance of the tissue and instantaneously adjust the generator output to maintain the desired power.

Available output modes include:

Monopolar

- Cut: clean, precise cut in tissue, with little or no hemostasis
- Blend: blended waveform for slower cutting and additional hemostatis
- Hemostasis with division (HWD): optimized division of tissue with controlled hemostasis and minimal thermal damage to adjacent tissue
- Fulgurate: tissue coagulation by sparking
- Spray: fulguration with shallower penetration over larger tissue areas

Bipolar

- Low: precise, controlled desiccation of tissue
- Standard: general bipolar desiccation with consistent tissue effect
- Macro: rapid coagulation and bipolar cutting in a wide range of tissues

LigaSure vessel sealing

- Seals vessels (arteries, veins, pulmonary arteries, pulmonary veins, lymph) 7mm and less, and tissue bundles

The monopolar Cut, Blend, Fulgurate, and Spray output modes are designed for use with conventional handswitching or footswitching electrosurgical devices. The three bipolar output modes are designed for use with conventional handswitching or footswitching electrosurgical bipolar forceps. When using conventional electrosurgical devices, the user selects the mode and desired power using a touch screen display on the generator.

All monopolar output modes, including HWD, may be used with Valleylab electrosurgical devices with surgeon power control. The surgeon power control devices utilize Covidien EbD Smart™ connector technology that allows the generator to identify the type of device in use. After recognizing the device type, the generator establishes five power zones for each output mode. The generator defaults to power zone 3, but the surgeon may select an alternate power zone using the touch screen. From the sterile field, the surgeon can then use the slider switch on instruments so equipped to select the desired power setting within the selected power zone. The surgeon activates the desired output mode (CUT, HWD, COAG) using the buttons on the device. The surgeon also has the option of using the touch screen

controls to select power levels outside the pre-established power zones to accommodate unusual surgical situations.

Monopolar electrosurgery requires the use of a patient return electrode ("return pad" or "grounding pad") with Valleylab REM™ return electrode monitoring. The REM system continuously verifies contact between the patient and pad to prevent pad site burns. (Valleylab REM™ electrodes were initially cleared for marketing on K822572, and have been used on all Valleylab electrosurgical generators since that time.) Bipolar devices and LigaSure vessel sealing devices do not require patient return electrodes

The ForceTriad™ vessel sealing mode is designed for use with LigaSure vessel sealing devices. The LigaSure™ devices utilize Smart connector technology to allow the generator to recognize the device in use and set the generator output accordingly.

No changes are being made to the design operation, or intended use of the any of the current systems except a revision to the software to allow the ForceTriad to interface with an Integrated Operating Room (OR) system. As of this date, the only cleared system which has demonstrated compatibility with the ForceTriad is the Olympus EndoAlpha endosurgery system, cleared on February 15, 2011. Refer to 510(k) K102763.

5. Intended Use

The ForceTriad™ generator is a full-featured electrosurgical generator intended for open and laparoscopic surgical procedures where the surgeon requires electrosurgical cutting, coagulation, or vessel sealing (tissue fusion) in general, urologic, thoracic, plastic and reconstructive, arthroscopic, gynecologic and similar surgery. The ForceTriad™ generator is intended for use in the operating room, surgery center, or clinic. The generator has both monopolar and bipolar outputs that accommodate standard electrosurgical devices and Valleylab electrosurgical devices with surgeon power control. The ForceTriad™ generator also incorporates the functionality of the Valleylab LigaSure™ vessel sealing system, and accepts Valleylab LigaSure™ devices.

Covidien makes the following recommendations with regard to the use of the ForceTriad™ electrosurgical generator.

- *Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause a pacemaker to enter*

an asynchronous mode or block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical or tissue fusion appliances is planned in patients with cardiac pacemakers.

- *If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical or tissue fusion procedure. Electrosurgery or tissue fusion may cause multiple activations of ICDs.*

Covidien recommends against the use of laparoscopic surgery on pregnant patients.

LigaSure tissue fusion has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this function for these procedures.

6. Summary of Technology Characteristics

The only change associated with this 510(k) is a software change. The software change allows the generator to interface with the Olympus EndoAlpha endosurgery system, manufactured by Olympus Medical Systems Corporation, Center Valley, PA. This Integrated OR system is used to control multiple pieces of equipment in the OR environment. The Technological Characteristics of the ForceTriad™ have not changed.

7. Summary of Non-clinical testing

Extensive software validation was conducted to qualify the software changes. Bench testing with a simulated Integrated OR System was conducted as well as testing with an actual system, the Olympus Medical Systems EndoAlpha system. The EndoAlpha system received 510(k) clearance on February 15, 2011. Refer to K102763. In addition, any new testing required by the new revisions of the relevant safety standards was also conducted.

8. Summary of Clinical testing

No clinical testing was conducted

9. Conclusion

Based on the information provided, Covidien concludes that the modification to the ForceTriad that adds the Integrated OR feature is substantially equivalent to the predicate device. The software modifications that allow communication of the ForceTriad with the Olympus EndoAlpha endosurgery system add no new questions of Safety and Efficacy, and these changes have no impact on the performance, function or intended use of the ForceTriad.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien
% Mr. Ben Cordileone
Regulatory Affairs Manager
5920 Longbow Drive
Boulder, Colorado 80301

MAY - 6 2011

Re: K102913
Device Name: Force Triad™ Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 15, 2011
Received: April 18, 2011

Dear Mr. Cordileone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102913

Device Name: Force Triad™ Electrosurgical Generator

Indications for Use:

The indications for use include general (including urologic, thoracic, plastic and reconstructive, arthroscopic), laparoscopic, and gynecologic procedures where electrosurgical cutting and coagulation of tissue, and sealing (fusion) of vessels and tissue bundles is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholesystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesilysis, oophorectomy, etc. Vessels (arteries, veins, pulmonary arteries, pulmonary veins, lymph) 7mm and smaller in diameter, and bundles as large as will fit in the jaws of the devices can be sealed with the LigaSure™ vessel sealing (tissue fusion) output.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102913